510(k) Special
Polygram '98 Esophageal Manometry Testing Application

510(k) Summary

Submitters Name and Address:

Medtronic Functional Diagnostic A/S
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Trade name, common name

Device Trade Name	Common/Classification Name
Polygram '98 Esophageal Manometry Testing Application	Esophageal Manometry System

Device Class:

The Esophageal Manometry Application System has been classified as Class II, 78 FFX.

Predicate Device Information:

The predicate device is the Polygram '98 Esophageal Manometry Testing Application, K992713, November 10, 1999.

Intended use:

The Polygram'98 Esophageal Manometry Testing Applications intended use is to record, store view and analyze data on line in the gastrointestinal tract to assist in the diagnosis of gastrointetisnal disorders. This is the same intended use as previously cleared for the Polygram'98 Esophageal Manometry Application, K992713.

Device description:

The main tasks when performing a manometry procedure with the system are:

- Prepare equipment including calibration
- Enter patient/study demographic information

- Perform procedure and obtain relevant data
- review, analysis and post procedure activities
- Create and print a report

Besides manometry the system through the modifications is able to measure pH simultaneously, to indicate the presence of acid at the point of measure in the esophagus, and to make an interface with the Medtronic Catheter Puller.

Assessment of non-clinical performance data for equivalence:
Verifications results shows that the enhanced system performs as its predicate system.

Assessment of clinical performance data for equivalence:
Clinical trials are not performed. This new system doesn't raise any new safety or performance issues.

Biocompatability:
Not applicable .

Sterilization:
Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2001

Ms. Tove Kjaer
Regulatory Affairs Specialist
Medtronic Functional Diagnostics
Tonsbakken 16 - 18
DK-2740 Skovlunde
DENMARK

Re: K010130
Polygram '98 Esophageal Manometry Testing Application
(Modified Software)
Dated: January 12, 2001
Received: January 16, 2001
Regulatory Class: II
21 CFR §876.1725/Procode: 78 FFX

Dear Ms. Kjaer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indication for Use Statement

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510(k) Number (if known): K010130

Device Name: **Polygram'98 Esophageal Manometry Testing Application**

Indications for Use:

The Polygram'98 Esophageal Manometry Testing Application is intended to record, store, view and analyze data on line in the gastrointestinal tract to assist in the diagnoses of gastrointestinal disorders.

MRI Compatibility Statement:

The Polygram '98 Esophageal Manometry Testing Application is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010130